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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,539	BUTZ ET AL.	
	Examiner	Art Unit	
	Laura B. Goddard, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed March 5, 2007 in response to the Office Action of September 8, 2006, is acknowledged and has been entered. Previously pending claims 1-57 are canceled. New claims 58-64 are added. Claims 58-64 are currently being examined.

New Rejection

(based on new considerations)

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claim 58 is rejected under 35 U.S.C. 101 because the claimed invention, **a peptide**, is directed to non-statutory subject matter.

The claims read on **a peptide** that is found in nature. Products of nature do not constitute patentable subject matter as defined in 35 USC 101. See MPEP 2105. Since a peptide does not exist in nature in purified form, it is suggested that Applicant use the language "isolated" or "purified" in connection with the peptide to identify a product that is found in nature.

New Rejection

(necessitated by amendments)

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 58-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a WRITTEN DESCRIPTION rejection.

The claims are drawn to a peptide which sensitizes cells for apoptosis comprising an amino acid sequence **at least 90% identical to SEQ ID NO:127** and which is capable of binding to livin-β.

The specification discloses SEQ ID NO:127 that binds to livin-β (Table 3; Examples 3-5). The specification does not disclose any other amino acid sequences at least 90% identical to SEQ ID NO:127 and which are capable of binding to livin-β as broadly encompassed in the claims.

A search of the prior and current art reveals that the art does not teach a peptide at least 90% identical to SEQ ID NO:127 and is capable of binding to livin-β, hence the art does not provide a representative number of species to support adequate written

description for the broad genus of amino acid sequences at least 90% identical to SEQ ID NO:127 and which are capable of binding to livin-β.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a recitation of "amino acid sequences at least 90% identical to SEQ ID NO:127 and which are capable of binding to livin-β". Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. The claims do not identify which 90% of SEQ ID NO:127 must be conserved among the variants to bind to livin-β, hence the conserved structure among the claimed amino acid sequences at least 90% identical to SEQ ID NO:127 required for binding to livin-β is not adequately described.

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that " [a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure,

formula, [or] chemical name', of the claimed subject matter sufficient to distinguish it from other materials. " Id. At 1567, 43 USPQ2d at 1405. The court also stated that:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by show[ing] that an

invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a product itself logically cannot adequately describe a method of using that product.

Thus, the instant specification may provide an adequate written description of amino acid sequences at least 90% identical to SEQ ID NO:127 and which are capable of binding to livin-β, per Lilly by structurally describing representative amino acid sequences at least 90% identical to SEQ ID NO:127 and which are capable of binding to livin-β or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not directly describe amino acid sequences at least 90% identical to SEQ ID NO:127 and which are capable of binding to livin-β useful

in the claimed invention in a manner that satisfies either the Lilly or Enzo standards. Although the specification discloses SEQ ID NO:127 that binds to livin-β, this does not provide a description of the broadly claimed amino acid sequences at least 90% identical to SEQ ID NO:127 and which are capable of binding to livin-β that would satisfy the standard set out in Enzo because the specification provides no functional characteristics coupled to structural features.

Further, the specification also fails to describe amino acid sequences at least 90% identical to SEQ ID NO:127 and which are capable of binding to livin-β by the test set out in Lilly because the specification describes only SEQ ID NO:127. Therefore it necessarily fails to describe a representative number of such species.

Thus, the specification does not provide an adequate written description of amino acid sequences at least 90% identical to SEQ ID NO:127 and which are capable of binding to livin-β that is required to practice the claimed invention. Since the specification fails to adequately describe the product to which the claimed method uses, it also fails to adequately describe the method.

Rejection Maintained

Claim Rejections - 35 USC § 112

4. New claim 63 (formerly claims 39-41 drawn to a medicament for the treatment of cancer) is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains,

or with which it is most nearly connected, to make and/or use the invention (see previous Office Action section 11).

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claim is drawn to a **pharmaceutical composition for the treatment of cancer** comprising the peptide of claim 58 and a pharmaceutically-acceptable carrier, optionally in combination with an intercalating agent.

The specification discloses SEQ ID NO:127 as peptide number 41 in Table 2 or peptide number 75 according to inventors numbering system (p. 4, lines 3-5). SEQ ID

NO:127 specifically binds the IAP livin-β and not to any other IAPs tested (Table 3). Example 4 of the specification discloses that HeLa and melanoma cells transfected with SEQ ID NO:127 blocked the growth of the cells which were livin-β positive, and did not affect the growth of livin-β negative cells (p. 18). Example 5 of the specification discloses fusing SEQ ID NO:127 to poly-arginine R9 (an internalization sequence), and administering the fusion complex to HeLa cells. Ectopic expression of the peptide led to a sensitization of livin-positive cells for pro-apoptotic drugs such as doxorubicin. Administration of doxorubicin resulted in an increased concentration of active caspase (Fig. 4) and the increased caspase-3 activity directly correlated with an increased cleavage of the caspase-3 substrate PARP and an increase of apoptosis of HeLa cells (p. 18).

One cannot extrapolate the disclosure of the specification to the scope of the claims because the specification does not provide guidance or examples for the claimed composition functioning to treat cancer as a pharmaceutical. The specification discloses sensitization of HeLa cells to apoptosis upon administration of SEQ ID NO:127 fused to poly-arginine R9 and administration of doxorubicin (Example 5). However, the specification does not provide guidance or examples for treating cancer *in vivo*. Those of skill in them art recognize that in vitro assays and or cell-cultured based assays are generally useful to observe basic physiological and cellular phenomenon such as screening the effects of potential drugs. However, clinical correlations are generally lacking. The greatly increased complexity of the in vivo environment as compared to the very narrowly defined and controlled conditions of an in- vitro assay does not permit a

single extrapolation of in vitro assays to human diagnostic efficacy with any reasonable degree of predictability. In vitro assays cannot easily assess cell-cell interactions that may be important in a particular pathological state. Furthermore it is well known in the art that cultured cells, over a period time, lose phenotypic characteristics associated with their normal counterpart cell type. Freshney (Culture of Animal Cells, A Manual of Basic Technique, Alan R. Liss, Inc., 1983, New York, p4) teach that it is recognized in the art that there are many differences between cultured cells and their counterparts *in vivo*. These differences stem from the dissociation of cells from a three-dimensional geometry and their propagation on a two-dimensional substrate. Specific cell interactions characteristic of histology of the tissue are lost. The culture environment lacks the input of the nervous and endocrine systems involved in homeostatic regulation in vivo. Without this control, cellular metabolism may be more constant in vitro but may not be truly representative of the tissue from which the cells were derived. This has often led to tissue culture being regarded in a rather skeptical light (p. 4, see Major Differences *In Vitro*). Further, Dermer (Bio/Technology, 1994, 12:320) teaches that, "petri dish cancer" is a poor representation of malignancy, with characteristics profoundly different from the human disease. Dermer teaches that when a normal or malignant body cell adapts to immortal life in culture, it takes an evolutionary type step that enables the new line to thrive in its artificial environment. This step transforms a cell from one that is stable and differentiated to one that is not. Yet normal or malignant cells in vivo are not like that. The reference states that evidence of the contradictions between life on the bottom of a lab dish and in the body has been in the scientific

literature for more than 30 years. Clearly it is well known in the art that cells in culture exhibit characteristics different from those in vivo and cannot duplicate the complex conditions of the *in vivo* environment involved in host-tumor and cell-cell interactions. Given the teaching of the art, a "pharmaceutical composition for the treatment of cancer" comprising SEQ ID NO:127 or an amino acid sequence at least 90% identical to SEQ ID NO:127 and which is capable of binding to livin-β would not predictably function to treat cancer as inferred by the claim and contemplated by the specification.

In re Brana 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995) demonstrates the criteria needed for enablement of a claimed product for pharmaceutical use. The Applicants in *In re Brana* claimed a chemical compound capable of treating cancer, wherein the chemical compound was structurally similar to known compounds that have known *in vivo* ability to treat tumors, and more importantly, the Applicant provided *in vivo* data that the claimed compound could treat tumors in mice, hence the claimed chemical compound was enabled for treating tumors. In the instant application, unlike in *In re Brana*, a search of the current and prior art does not teach or enable the claimed composition or any structurally and functionally similar peptides of the composition for treating cancer or functioning as a pharmaceutical. Additionally, the instant application, unlike in *In re Brana*, does not provide examples or guidance for any pharmaceutical *in vivo* data, particularly regarding the treatment of cancer. Hence, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

A search of the prior and current art does not reveal peptides structurally similar to SEQ ID NO:127 that would predictably function as a pharmaceutical. It is noted that

MPEP 2164.03 teaches that "the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability of the art. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The amount of guidance or direction refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as how to make and use the invention in order to be enabling."

Therefore, in view of the state of the art, the breadth of the claims, lack of guidance in the specification, and the absence of working examples, it would require undue experimentation for one skilled in the art to practice the invention as claimed.

Response to Arguments

Restriction

5. Applicants continue to traverse the restriction requirement with regards to the search of at least 10 sequences not being a search burden on the Examiner (p. 6-7).

The restriction requirement remains final and Examiner maintains arguments that a search of multiple sequences invokes a high search burden on Examiner. Examiner's arguments for the overwhelming search burden of multiple structurally different

sequences are supported by the USPTO's published pre-OG notice: http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/sequence02212007.pdf (included in Office Action for Applicants' convenience, see "Examination of Patent Applications Containing Nucleotide Sequences", p. 1-3). The overwhelming and expanding database for nucleotide sequences also applies to amino acid sequence searches.

Claim Rejections - 35 USC § 112-enablement

6. Applicants argue that they are not required to provide evidence of clinical or *in vivo* studies to claimed methods of treatment and point to *In re Brana* (p. 8).

The argument has been considered and is not found persuasive because the claimed composition is not enabled for functioning predictably as a pharmaceutical or for treating cancer as claimed. *In re Brana* teaches that *in vivo* or clinical data is not required when a structurally and functionally similar peptide or agent is already enabled in the prior or current art, hence it would not be undue experimentation for one of skill in the art to treat cancer or use the claimed composition as a pharmaceutical if the composition comprises a compound structurally and functionally similar to an agent that is already enabled for cancer treatment. However, in the instant application, unlike in the case of *In re Brana*, a search of the current and prior art does not teach or enable the claimed composition or any structurally and functionally similar peptides of the composition for treating cancer or for functioning as a pharmaceutical. Additionally, the

instant specification does not provide any *in vivo* data for the claimed composition functioning as a pharmaceutical or for treating cancer. Given the lack of guidance and examples from the specification for the claimed composition functioning as a pharmaceutical or for treating cancer, the lack of enabling art, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

7. Applicants ask for reasons for a conclusion of lack of correlation between clinical efficiency and an *in vitro* or *in vivo* animal model and state Examiner has not provided reasons for lack of enablement with regards to extrapolating *in vitro* data to cancer treatment *in vivo* (p. 9).

The arguments have been considered and are not found persuasive. Examiner provided art teaching the discrepancy between cultured cells and the *in vivo* environment that contribute to the lack of correlation between an *in vitro* effect on cells and actual treatment or pharmaceutical effect *in vivo* because the *in vitro* cells are not representative of the *in vivo* cells and environment. For example (see section 11 of previous Office Action): "Freshney (Culture of Animal Cells, A Manual of Basic Technique, Alan R. Liss, Inc., 1983, New York, p4) teach that it is recognized in the art that there are many differences between cultured cells and their counterparts *in vivo*. These differences stem from the dissociation of cells from a three-dimensional geometry and their propagation on a two-dimensional substrate. Specific cell interactions characteristic of histology of the tissue are lost. The culture environment lacks the input of the nervous and endocrine systems involved in homeostatic regulation

in vivo. Without this control, cellular metabolism may be more constant in vitro but may not be truly representative of the tissue from which the cells were derived. This has often led to tissue culture being regarded in a rather skeptical light (p. 4, see Major Differences *In Vitro*)". Further Examiner argued: "Dermer (Bio/Technology, 1994, 12:320) teaches that, "petri dish cancer" is a poor representation of malignancy, with characteristics profoundly different from the human disease. Dermer teaches that when a normal or malignant body cell adapts to immortal life in culture, it takes an evolutionary type step that enables the new line to thrive in its artificial environment. This step transforms a cell from one that is stable and differentiated to one that is not. Yet normal or malignant cells in vivo are not like that. The reference states that evidence of the contradictions between life on the bottom of a lab dish and in the body has been in the scientific literature for more than 30 years. Clearly it is well known in the art that cells in culture exhibit characteristics different from those in vivo and cannot duplicate the complex conditions of the *in vivo* environment involved in host-tumor and cell-cell interactions". While *in vitro* systems are useful for drug screening, they do not predictably determine cancer treatment or pharmaceutical effects *in vivo*, hence one of skill in the art could not reasonably extrapolate the *in vitro* assay to the treatment of cancer or pharmaceutical effects of an agent *in vivo*.

Despite the Examiner citing art supportive for the lack of correlation and predictability between *in vitro* and *in vivo* systems, Applicants ask for reasons for lack of enablement with regards to extrapolating *in vitro* data to cancer treatment *in vivo*. In addition to Freshney (above) and Dermer (above), Zips et al (2005, In Vivo, 19:1-7)

teach "It is obvious that cells in culture represent an artificial and simplified system. Unlike the situation *in vitro*, a tumor is a 3-dimensional complex consisting of interacting malignant and non-malignant cells. Vascularization, perfusion and, thereby drug access to the tumor cells are not evenly distributed and this fact consists an important source of heterogeneity in tumor response to drugs that does not exist *in vitro*. **Therefore, prediction of drug effects in cancer patients based solely on *in vitro* data is not reliable and further evaluation in animal tumor systems is essential** (p. 3, col. 2)". Given the recognition in the art that *in vitro* assays are not representative of *in vivo* systems, one of skill in the art could not reasonably extrapolate the results of an *in vitro* assay to the treatment of cancer or pharmaceutical effects *in vivo* for a peptide composition. Contrary to Applicants' assertion that *in vitro* cell assays in cell lines are generally well recognized by those of ordinary skill in the art as predictive of *in vivo* efficacy in predicting cancer therapy and apoptosis, the art teaches otherwise as stated above.

8. All other rejections recited in the Office Action mailed September 8, 2006 are hereby withdrawn.

9. **Conclusion:** No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 7:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura B Goddard, Ph.D.
Examiner
Art Unit 1642

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